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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVARTIS AG and NOVARTIS
PHARMACEUTICALS CORPORATION,

Plaintiffs,

v.

NOVADOZ PHARMACEUTICALS LLC, *et
al.*,

Defendants.

No. 25cv849 (EP) (JRA)

OPINION

PADIN, District Judge.

This Court granted Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation's (together, "Novartis") motion for a preliminary injunction, D.E. 4 ("PI Motion" or "PI Mot."), against Defendants MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and Novadoz Pharmaceuticals LLC (collectively, "MSN") for alleged infringement of Novartis's trademark and trade dress rights. D.E. 32 ("Opinion"). Defendants have appealed that decision to the Third Circuit, D.E. 35, and move to stay the preliminary injunction pending that appeal. D.E. 37 ("Stay Motion" or "Stay Mot.").

The Court understands the imperative nature of the matter before it. After careful consideration of the arguments before it and the circumstances the parties face pending appeal before the Third Circuit, the Court will **GRANT** the Stay Motion.

I. BACKGROUND

Novartis is a pharmaceutical company that manufactures ENTRESTO®, an FDA-approved heart failure prescription medication that was launched in 2015. D.E. 1 ("Compl.") ¶¶ 3, 52-53. It is the number one heart failure brand prescribed by physicians and has helped reduce the risk of

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death and hospitalization for over 2.5 million patients. *Id.* ¶ 3. Novartis's generics partner is Sandoz, which used to be Novartis's wholly-owned generics division prior to its sale. *Id.* ¶ 7.

ENTRESTO® is offered in three doses, each in a unique combination of size, shape, and color. *Id.* ¶ 59. The Low Starting Dose, a 24/26 mg dose, is a violet white oval tablet, measuring 13.1 mm x 5.2 mm; the Recommended Starting Dose, a 49/51 mg dose, is a pale yellow oval tablet, measuring 13.1 mm x 5.2 mm; and the Target Dose, a 97/103 mg dose, is a light pink oval tablet, measuring 15.1 mm x 6.0 mm. *Id.* Images of the drug show that the face of each pill is marked "NVR." D.E. 4-4 ("Valazza Decl.") ¶ 15.

Novartis alleges that MSN will imminently bring to market a generic version of ENTRESTO®, under the NOVADOZ name, intending to confuse healthcare providers and consumers into believing NOVADOZ is affiliated with Novartis (the "MSN Drug"). Compl. ¶¶ 6-7. Novartis avers that the physical similarities between NOVADOZ and ENTRESTO®, as well as NOVADOZ's name—purportedly intended to invoke a combination of Novartis and Sandoz—reflect an intentional effort to deceive the marketplace. *Id.* ¶ 7. The launch of NOVADOZ, however, hinges on proceedings before the Federal Circuit. *Id.* ¶ 89. Patent barriers also currently prevent NOVADOZ and other generics from launching before July 16, 2025. D.E. 49.

MSN submitted an Abbreviated New Drug Application ("ANDA") for its generic equivalent to ENTRESTO® on July 7, 2019. D.E. 13-7 ("Nithiyanandam Decl.") ¶ 3. For an ANDA to receive FDA approval, the generic drug product must contain the same active ingredient(s) of the branded drug, come in the same dosage form, and deliver the same dose. *Id.* ¶ 4. As a result, the MSN Drug also comes in three tablets: a 24/26 mg tablet, 49/51 mg tablet, and a 97/103 mg tablet. *Id.* ¶ 5. MSN's 2019 ANDA contained proposed dimensions of the drug products, respectively measuring 10 x 4 mm, 13 x 5.10 mm, and 15 x 5.9 mm. *Id.* ¶ 6. Images of

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the MSN Drug show that the face of each pill is marked “M.” *Id.* The pills are not identical, but they are similar.

| PARAMETERS | REFERENCE LISTED DRUG | PROPOSED DRUG PRODUCT |
|---|---|--|
| Strengths | 24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg | 24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg |
| Configuration | | |
| 24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg | Bottle of 60's and 180's | Bottle of 60's and 180's |
| 24 mg/ 26 mg |  |  |
| 49 mg/ 51 mg |  |  |
| 97 mg/ 103 mg |  |  |
| Dimensions | | |
| 24 mg/ 26 mg | 13.35 x 5.33 | 10.00 X 4.00 mm |
| 49 mg/ 51 mg | 13.25 x 5.30 | 13.00 X 5.10 mm |
| 97 mg/ 103 mg | 15.34 x 6.12 | 15.00 X 5.90 mm |
| Active Ingredient | Sacubitril and Valsartan | Sacubitril and Valsartan |

Id.

Novartis brings claims for trademark infringement, false designation of origin, trade dress infringement, and unfair competition. *Id.* ¶¶ 128-205. It argues that patients will face imminent health risks as the MSN Drug does not have identical FDA-approved dosing instructions and will be confused with ENTRESTO®. PI Mot. at 3. Specifically, the ENTRESTO® label and prescribing information directs certain patients to start with a low starting dose, while the MSN Drug label and prescribing information does not. *Id.* at 14-15. Novartis argues it will face reputational damage and loss of trade in the form of lost sales. *Id.* at 37.

II. PROCEDURAL HISTORY

Novartis’s motion for a preliminary injunction also sought a temporary restraining order. PI Mot. This Court denied Novartis’s request for temporary restraints but ordered expedited briefing on the preliminary injunction motion. D.E. 7. MSN’s opposition, D.E. 13 (“PI Opp’n”),

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and Novartis's reply, D.E. 17 ("PI Reply"), followed. The Court then issued the Opinion. Shortly thereafter, MSN moved to stay. Stay Mot. Novartis opposed, D.E. 42 ("Stay Opp'n"), and MSN replied, D.E. 44 ("Stay Reply").¹

III. LEGAL STANDARD

As the standard for a stay or an injunction pending appeal "is essentially the same as that for obtaining a preliminary injunction," the Court considers the preliminary injunction factors in determining whether to grant the Stay Motion. *Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dep't of Health and Human Servs.*, No. 13-1144, 2013 WL 1277419, at *1 (3d Cir. 2013). Novartis was required to demonstrate:

(1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief.

Kos Pharm., Inc. v. Andrx Corp., 369 F.3d 700, 708. (3d Cir. 2004). "[W]hen evaluating whether interim equitable relief is appropriate, 't]he first two factors of the traditional standard are the most critical.'" *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017) (quoting *Nken v. Holder*, 556 U.S. 418, 424 (2009)). But "[a] plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate." *Conestoga*, 2013 WL 1277419, at *1 (quoting *NutraSweet Co. v. Vit-Mar Enter., Inc.*, 176. F.3d 151, 153 (3d Cir. 1999)).

IV. ANALYSIS

The Court first addresses functionality before turning to MSN's primary argument that the Court did not implement the proper burden-shifting framework to prove irreparable harm in

¹ The Court also indicated it was considering *sua sponte* reconsidering its Opinion and provided the parties an opportunity to brief the issue. D.E. 43. The parties did so. D.E.s 45-46. The Court addresses the Stay Motion and does not *sua sponte* reconsider its Opinion because "[a]s a general rule, the timely filing of a notice of appeal . . . divest[s] a district court of its control over those aspects of the case involved in the appeal." *Venen v. Sweet*, 758 F.2d 117, 120 (3d Cir. 1985).

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trademark cases. Stay Mot. at 8. Novartis agrees that the Court applied the wrong framework for irreparable harm. Stay Opp'n at 11. The Court also agrees. The Court then addresses whether Novartis will suffer irreparable harm if the Court's preliminary injunction is not maintained for the time being. The Court finds that Novartis will not suffer irreparable harm if the Court stays its preliminary injunction for the pendency of MSN's appeal. As explained below, the parties' helpful reflection of the record in briefing the Stay Motion, the application of the appropriate legal framework, and attention to the parties' posture on appeal here in the Third Circuit and before the Federal Circuit merit staying this Court's preliminary injunction pending MSN's appeal. Therefore, the Court will grant the Stay Motion.

A. Likelihood of Success on the Merits

“A plaintiff must prove three elements to establish trade dress infringement under the Lanham Act: ‘(1) the allegedly infringing design is nonfunctional; (2) the design is inherently distinctive or has acquired secondary meaning; and (3) consumers are likely to confuse the source of the plaintiff’s product with that of the defendant’s product.’” *Fair Wind Sailing, Inc. v. Dempster*, 764 F.3d 303, 309 (3d Cir. 2014) (quoting *McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC*, 511 F.3d 350, 357 (3d Cir. 2007)). This Court is also mindful of the Third Circuit’s instruction that courts should “caution against the over-extension of trade dress protection.” *Shire US Inc. v. Barr Labs., Inc.*, 329 F.3d 348, 358 (2003). Trade dress protection should extend “only to incidental, arbitrary or ornamental product features which identify the product’s source.” *Shire*, 329 F.3d at 353. Upon close consideration of the parties’ arguments, the Court finds that the allegedly infringed design is functional² and that Novartis is therefore

² The Court recognizes that its holding here is in conflict with its previous holding. Opinion at 6-10. The Court appreciates the parties’ close attention to the issues in briefing the Stay Motion and notes that courts sometimes get things wrong. *See, e.g., Thompson Reuters Enter. Ctr. GmbH v.*

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unlikely to succeed on the merits of its trade dress infringement claim on appeal. The Court also finds that in any event, Novartis is unlikely to suffer irreparable harm in the absence of injunctive relief during the pendency of the appeal.

1. *Non-functionality*

MSN argues that it is likely to succeed on the merits of its appeal because the Court erred in finding non-functionality. Stay Mot. at 17-21. The Court agrees.

“Trade dress, a subset of trademark, protects distinctive choices (like size, shape, and color) that make up ‘the overall look of a product.’” *PIM Brands Inc. v. Haribo of Am. Inc.*, 81 F.4th 317, 321 (3d Cir. 2023) (quoting *Ezaki Glico Kabushiki Kaisha v. Lotte Int’l Am. Corp.*, 986 F.3d 250, 255 (3d Cir. 2021)). To be functional, the trade dress as a whole “need only be useful, not essential.” *Ezaki Glico*, 986 F.3d at 258. And [t]he question is not whether the product or feature is useful, but whether ‘the particular shape and form’ chosen for that feature is.” *Id.* at 257 (quoting 3 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 7:70 (5th ed. 2020)).

“A nonfunctional feature is one that ‘is unrelated to the consumer demand . . . and serves merely to identify the source of the product or business.’” *EBIN New York, Inc. v. Kiss Nail Prods., Inc.*, No. 23-2369, 2024 WL 1328029, at *6 (D.N.J. Mar. 28, 2024) (quoting *Fair Wind*, 764 F.3d at 311). “Conversely, a functional feature is ‘one that is essential to the use or purpose of the article, affects the cost or quality of the article, or one that, if kept from competitors, would put them at a significant non-reputation-related disadvantage.’” *Id.* (quoting *Fair Wind*, 764 F.3d at 310). The Court evaluates the color, size, and shape of ENTRESTO® and finds that all aspects are functional.

Ross Intel. Inc., No. 20-cv-613-SB, 2025 WL 458520, at *1 (D. Del. Feb. 11, 2025) (“A smart man knows when he is right; a wise man knows when he is wrong. Wisdom does not always find me, so I try to embrace it when it does—even if it comes late, as it did here.”).

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a. Color-Coding and Size

MSN argues that communication of functional information to patients—what drug each pill is and what dose it contains—is evidenced by the colors and sizes of the ENTRESTO® pills. PI Opp’n at 13. It further indicates that consistent color-coding systems can reduce therapeutic errors in other drug regimens. D.E. 13-40 (“Clark Decl.”) ¶ 53. On the other hand, Novartis attests that it is unaware of “any functional reason why the Low Starting Dose and the Recommended Starting Dose need to be smaller than the Target Dose. These sizes could be made uniform without impacting the efficacy of the formulation.” Valazza Decl. ¶ 20. According to Novartis, the selection of size and shape of the pills, therefore, was purely based on a desire to differentiate the tablets from competitors’ trade dresses. *Id.* ¶ 16. And while ENTRESTO® comes in three doses, patients can progress up from the lower doses to the target dose. D.E. 4-11 (“Nayeri Decl.”) ¶ 17. Patients typically take their tablets twice daily, indefinitely, irrespective of the dose on which they begin their regimens. *Id.* ¶ 18. According to Novartis, there is no need to distinguish between daily doses, because once adjusted to a particular dosage, patients remove the others from their medication cycle. PI Reply at 4 n.4.

Novartis’s position, in sum, is that the ENTRESTO® trade dresses were designed to differentiate the drug in the heart failure treatment market, rather than to improve cost, quality, or efficacy. PI Mot. at 17. MSN counters that under Third Circuit precedent, color-coding of drugs to convey dosage information is functional. PI Opp’n at 12 (citing *Shire*, 329 F.3d 348). Novartis does not dispute that the color-coding and size distinctions between dosages is functional but instead disputes that the particular colors chosen “do not confer an edge in usefulness.” Stay Opp’n at 25. The Court agrees with MSN and addresses the particular colors next. *See infra* IV. A. 1. b.

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The Court finds that the distinctions between doses—based on color-coding and size—are likely functional because patients, physicians, and pharmacists rely on these distinctions of ENTRESTO® strengths to distinguish between the three different doses. Stay Reply at 10. The Court agrees with MSN that the color-coding and size of ENTRESTO® provides some “degree of clinical functionality”—just as Adderall did in *Shire*—because the record shows that ENTRESTO® patients, like Adderall patients, require some initial dosage titration and intermittent dosage adjustment. *Shire*, 329 F.3d at 354 (crediting the record that “color coding of a particular preparation of mixed amphetamine salts tablets confers a substantial degree of clinical functionality for the patient in the titration/adjustment process”); *see also* PI Reply at 4 n.4; Nayeri Decl. ¶ 18; D.E. 17-1 (“Nayeri Rebuttal Decl.”) ¶ 30.

b. The Particular Colors

Novartis argues that even if using color to distinguish doses is functional, “there is no functional reason to use the colors of white-violet, light yellow, and light pink.” Stay Opp’n at 25. MSN argues that the particular colors are functional because by “using colors similar to those Entresto patients had become accustomed to,” MSN achieves “the functional benefit of helping existing Entresto patients identify MSN’s Drug as the correct drug.” Stay Reply at 10 n.8.

The Court recognizes that MSN’s identified feature of “helping existing Entresto patients identify the correct drug only by using colors similar to those Entresto patients had become accustomed to” inures to MSN’s benefit in part because it associates MSN’s Drug with Novartis’s product. The Court agrees that the particular colors that Novartis chose were not innately functional. As the Third Circuit explained, “[f]or instance, though ironing-board pads need to use some color . . . to avoid noticeable stains, there is no functional reason to use green-gold in particular. Though French press coffeemakers need some handle, there is no functional reason to

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design the particular handle in the shape of a “C.” And though armchairs need some armrest, there is no functional reason to design the particular armrest as a trapezoid.” *Ezaki Glico*, 986 F.3d at 257-58.

But drug products can differ in nature compared to ironing board pads, coffeemakers, and armchairs. “[D]rug color cases have more to do with public health policy regarding generic drug substitution than with trademark law.” *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159, 169 (1995). Although there may have been no functional reason to have chosen violet white, pale yellow, and light pink in the first instance, those colors, once chosen can “come to represent to large numbers of those taking [the drugs] not its source but its ingredients and their effects.” *Shire*, 329 F.3d at 358 n.20. Consequently, the colors can become

functional to patients as well as doctors and hospitals; many elderly patients associate color with therapeutic effect; some patients comingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs.

Inwood Laby's, Inc. v. Ives Laby's, Inc., 456 U.S. 844, 853 (1982). As a result, generic manufacturers that fail to mimic the RLD’s color scheme can suffer “a significant disadvantage because the feature is ‘essential to the use or purpose of the article’ or ‘affects [its] cost or quality.’” *Qualitex Co.*, 514 U.S. at 169 (quoting *Inwood Laby's, Inc.*, 456 U.S. at 850 n.10). This problem is of particular significance for patient populations who suffer from chronic illnesses, regularly comingle medications, and depend on a drug product’s visual appearance to distinguish their medications from one another. *See Ives Laby's, Inc. v. Darby Drug Co., Inc.*, 488 F. Supp. 394, 399 (E.D.N.Y. 1980).³

³ The Second Circuit reversed in *Ives Laby's, Inc. v. Darby Drug Co.*, 638 F.2d 538 (2d Cir. 1981) *sub nom.*, but the Supreme Court in turn reversed the Second Circuit in *Inwood Laby's, Inc. v. Ives*

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The Court previously found that ENTRESTO®’s appearance “has an element of functionality” because it “can serve as useful visual cues for patients” and can provide “familiarity with a medication to be taken in seeming perpetuity.” Opinion at *9. The Court appreciates the parties’ thoughtful attention addressing the Declaration of Martin Shimer, the former Deputy Director of the FDA’s Office of Generic Drugs. D.E. 13-46 (“Shimer Decl.”). Shimer explains that mirroring the color scheme of the RLD helps to “ensure that patients are able to distinguish doses for similar products using the same functional cues as the color scheme of the branded RLD that a patient had been accustomed to receiving.” Shimer Decl. ¶ 47. Shimer further explains that this is routine practice across the generic industry and helps avoid the uncertainty that would arise from generics using a different tablet size, shape, or color for their products. *Id.* ¶ 48 (“Patients rely upon visual cues and other distinguishing factors such as color and shape to both identify the kind of medication they are taking and how many times a day they take that medication.”).

Considering the practical needs of patients with chronic illnesses and comorbidities who are often comingling multiple medications on a daily basis, the Court departs from the conclusion it reached in its prior Opinion. Analyzing functionality (or a lack thereof) of the particular colors of a drug product like ENTRESTO® differs in nature from the functionality of the particular colors chosen for products such as an ironing board pad. The Court therefore agrees with MSN and finds that the colors for ENTRESTO® are likely functional.

c. Size and Shape

Relatedly, MSN also argues that the Court failed to address its evidence that it chose the shape and size of its pills for functional reasons. Stay Mot. at 20; Nithiyanandam Decl. ¶ 12

Laby’s, Inc., 456 U.S. 844 (1982). On remand from the Supreme Court, the Second Circuit affirmed the district court. *Ives Laby’s, Inc. v. Darby Drug Co., Inc.*, 697 F.2d 291 (2d Cir. 1982).

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(“MSN’s pills are ovaloid-shaped because that shape is very easy for patients to swallow. Ovaloid-shaped pills are also easier and more cost-effective for MSN to manufacture, including because they allow for a simpler mold design, more efficient use of the mold space, and more efficient coating and packaging processes. Indeed, hundreds if not thousands of other drug companies choose that ovaloid shape for their tablets for these functional reasons.”). Although the Court agrees with Novartis that the functionality assessment turns on the plaintiff’s trade dress, the Court nevertheless finds that the ovaloid shape and the size of Novartis’s drug product are functional.

Shimer highlights the FDA’s Physical Attribute Guidance⁴ explaining the functionality of tablet size and shape. *Id.* (citing FDA Physical Attribute Guidance). For example, the FDA explains that survey data has shown “as many as 40 percent of Americans” have some difficulty swallowing tablets and capsules. FDA Physical Attribute Guidance at 2. “The size of the tablet or capsule influences esophageal transit, irrespective of patient factors and administration techniques.” *Id.* Tablet shape affects esophageal transit time too. *Id.* at 3 (“Studies in humans have also suggested that oval tablets may be easier to swallow and have faster esophageal transit times than round tablets of the same weight.”).

It is Novartis’s burden to show that the ENTRESTO® trade dress is non-functional. *Shire*, 329 F.3d at 353. Yet, Novartis does not dispute that the size and shape of ENTRESTO® possess functionality. Stay Opp’n at 28-30; PI Brief at 17-20; PI Reply at 3-5. Instead, Novartis argues that it chose the ENTRESTO® trade dress “to distinguish ENTRESTO® from competitors’ products.” D.E. 17 at 3. But “product design almost invariably serves purposes other than source identification.” *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 213 (2000). And here,

⁴ U.S. Food & Drug Admin., Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules: Guidance for Industry (June 2015), <https://www.fda.gov/media/87344/download> (hereinafter “FDA Physical Attribute Guidance”).

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even if Novartis chose the shape and size of ENTRESTO® to distinguish it from other medications, the shape and size still seem to affect administrability of the medication and transit time after ingestion. The Court therefore credits Shimer's declaration and the FDA Physical Attribute Guidance here and finds that, like the colors of ENTRESO®, the size and shape of Novartis's drug products are likely also functional.

Because size, shape, and color all appear to be functional features of ENTRESTO®, the Court finds that MSN established that it is likely to succeed on appeal, with respect to the merits of its trade dress infringement claim under the Lanham Act. *Fair Wind Sailing, Inc. v. Dempster*, 764 F.3d 303, 309 (3d Cir. 2014). The Court now considers whether Novartis will face irreparable harm if the Court stays its preliminary injunction during the pendency of MSN's appeal.

B. Irreparable Harm

The Trademark Modernization Act ("TMA") created a rebuttal presumption of irreparable harm, provided a likelihood of success on the merits is demonstrated. *Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 184-85 (3d Cir. 2022); 15 U.S.C. § 1116(a). "Because the TMA does not explain how its rebuttable presumption applies, courts follow the Federal Rules of Evidence in this context." *Aljess LLC v. Tun Tavern Legacy Foundation Inc.*, No. 24-2388, 2024 WL 4988972, at *10 (E.D. Pa. Dec. 4, 2024). Federal Rule of Evidence 301 states that "the party against whom a presumption is directed has the burden of producing evidence to rebut the presumption. But this rule does not shift the burden of persuasion, which remains on the party who had it originally." The Court, therefore, must ask "whether the rebuttal evidence is enough to allow a reasonable factfinder to conclude that irreparable harm is unlikely." *Nichino*, 44 F.4th at 185.

The Court acknowledges it used the incorrect framework in its Opinion. The Court, however, also acknowledges that because the Court here finds that MSN has shown that it is likely

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to succeed on the merits of its appeal, the statutory presumption does not apply to Novartis. Instead, Novartis must show that it “specifically and personally risks irreparable harm” during the pendency of the appeal. *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 562 F.3d 553, 557 (3d Cir. 2009); *see also Del. State Sportsmens’ Ass’n, Inc. v. Del. Dep’t of Safety & Homeland Sec.*, 108 F.4th 194, 204-05 (3d Cir. 2024) (“[Challengers] must show that, without a preliminary injunction, they will more likely than not suffer irreparable injury while proceedings are pending.”). “Grounds for irreparable injury include loss of control over reputation, loss of trade, and loss of good will,” but injuries “measured in solely monetary terms cannot constitute irreparable harm.” *Buzz Bee Toys, Inc.*, 20 F. Supp. 3d 483, 510 (D.N.J. 2014) (quoting *Kos Pharms.*, 369 F.3d at 726). Novartis argues that it will suffer irreparable harm through loss of control over its reputation and loss of trade in the form of lost sales. PI Mot. at 37-38. For the reasons explained below, the Court here finds that for the pendency of MSN’s appeal, MSN’s evidence persuasively shows that irreparable harm to Novartis is unlikely.

The Court begins by addressing its prior finding that Third Circuit precedent dictated the outcome of Novartis’s reputational harm theory. Opinion at *9 (quoting *Opticians Ass’n of Am. v. Ind. Opticians of Am.*, 920 F.2d 187, 195 (3d Cir. 1990)). In *Opticians Association*, the Third Circuit held that “likelihood of confusion is inevitable, when . . . the identical mark is used concurrently by unrelated entities.” *Id.* The Third Circuit agreed with the admonition that “[c]ases where a defendant uses an identical mark on competitive goods hardly ever find their way into the appellate reports. Such cases are ‘open and shut’ and do not involve protracted litigation to determine liability for trademark infringement.” *Id.* (quoting 2 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 23:7 (2d ed. 1984)). Here, however, the Court found it unlikely that trade dress protects the size, shape, and colors of ENTRESTO®. *See supra* IV. A.

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Without a mark, this case is not an “open and shut” one and *Opticians Association of America* does not require holding that irreparable harm is a given.

The Court must then address the merits of Novartis’s theory of reputational harm. Novartis argues that “*if* the MSN Drug is defective, causes severe side effects . . . , or otherwise leads to safety concerns,” Novartis’s reputation will suffer the consequences. PI Mot. at 37-38 (emphasis added). In particular, Novartis points to MSN’s proposed drug label, which omits dosing information that Novartis includes in its ENTRESTO® label. *Id.* Novartis’s expert, Dr. Nayeri, also states that physicians may inadvertently refer to the drug label for MSN’s Drug while prescribing ENTRESTO® and that reference to the label for MSN’s Drug could result in dosing errors, thereby causing harm to patients and drawing disdain from HCPs. PI Reply at 13 (citing Nayeri Decl. ¶¶ 30-45). Finally, Novartis raises concerns that MSN’s Drug has a higher risk of contamination by virtue of being manufactured in countries where some other drugs have had quality control problems. Nayeri Rebuttal Decl. ¶ 10. MSN calls this speculation. Stay Mot. at 11. The Court agrees with MSN.

Safety has long fallen under the purview of the FDA. *See, e.g., United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1369 (Fed. Cir. 2023). Here, the FDA has reviewed MSN’s proposed drug label. *See Novartis Pharms. Corp. v. Becerra*, No. 24cv2234 (DLF), 2024 WL 3823270, at *6 (D.D.C. Aug. 13, 2024) (crediting “the FDA’s judgment on [MSN’s proposed drug label], which is set forth in 10-pages of highly technical analysis, [as] thorough and well-reasoned”). In the absence of evidence indicating that MSN’s Drug actually is defective, will cause severe side effects, or will otherwise present safety concerns, the Court declines to assume that MSN’s Drug—which can launch only if approved by the FDA and deemed bioequivalent to ENTRESTO®—is not as safe. The Court also agrees with MSN that Novartis’s purported

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scenario—where Novartis’s reputation bears the blame when HCPs prescribe the wrong dose of ENTRESTO® after consulting the label for MSN’s Drug after being led astray by images of MSN’s Drug—is too speculative⁵ for the Court to rely on and is credibly disputed by the opinion of MSN’s expert Dr. Ardehali. PI Reply at 13; D.E.13-49 (“Ardehali Decl.”) ¶¶ 35-39. Indeed, Novartis’s expert opinions are hedged as scenarios that “could” occur. Ward Decl. ¶ 20 (“certain patients *could* receive a higher dose than is directed by the Entresto label”), ¶ 21 (“A patient . . . *could* believe the MSN Generic is Entresto”) (emphasis added in both); Nayeri Decl. ¶ 29 (“An HCP *could* inadvertently mix up two drugs based on their appearance or confusingly similar manufacturer names. . . . Exposure to that information *could* lead HCPs to consult the generic’s FDA-approved label and packaging insert . . . rather than through the branded drug’s FDA-approved label and packaging insert. . . . “HCP confusion—and the inadvertent reference to the generic’s prescribing information, rather than Entresto’s prescribing information—*could* lead to patient harm. A confused HCP *might* fail to prescribe a reduced dosing regimen”) (emphasis added in all). No particularized evidence indicates that these scenarios actually would occur.

And Novartis’s concerns that contamination issues may affect MSN’s Drug (and thereby Novartis’s reputation) simply because some other drug manufacturers have faced similar issues in those countries of manufacture, is not enough to show that Novartis *specifically* and *personally* risks irreparable harm. PI Mot. at 38; *Liberty Lincoln-Mercury, Inc.*, 562 F.3d at 557. Thus, the

⁵ Novartis also argues that this inadvertence will result in patients receiving MSN’s Drug instead of ENTRESTO®. PI Reply at 13. Novartis does not explain how a patient will nevertheless receive MSN’s Drug after a HCP erroneous reviews the label for MSN’s Drug and erroneously prescribes the wrong dose of ENTRESTO®. *Id.*

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Court agrees with MSN that Novartis has not shown that it is likely to face irreparable reputation-based harm.

The Court next addresses Novartis's economic-based theories of irreparable harm. Novartis argues that it will suffer loss of trade if "illegal substitution occurs or if confused patients request refills of the MSN Drug, rather than ENTRESTO®, through resources like Amazon Pharmacy or Medipod." PI Mot. at 38. Novartis also adds that it will lose sales to MSN. Robbins Decl. ¶¶ 18-27. Neither of Novartis's arguments are persuasive because Novartis provides no evidence that illegal substitution is likely to occur, nor does Novartis explain why its other injuries are not compensable by monetary damages. "The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." *In re Revel AC, Inc.*, 802 F.3d 558, 571 (3d Cir. 2015). Courts in this district and in others regularly find that lost sales are compensable injuries. *See, e.g., Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 501 (D.N.J. 2015) (collecting cases). This Court follows suit.

The parties have also clarified that irrespective of this Court's injunction, MSN is barred from launching its generic drug product before at least July 16, 2025. Stay Opp'n at 4-5 (citing *In re Entresto (Sacubitril/Valsartan) Patent Litig.*, No. 20-md-2930-RGA (D. Del.), D.E. 1823); *see also* D.E. 49 ("all patent barriers to MSN's entry will end by July 16, 2025"); D.E. 50 ("Novartis disagrees with MSN's representation that 'all patent barriers to MSN's entry will end by July 16, 2025 at the latest.'"). While this Court cannot predict the decisions of another, the Court is satisfied

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that any harm to Novartis resulting from a stay of this Court's injunction will be temporally limited and not irreparable.⁶

Having determined that the two "gateway factors" appropriately favor MSN, the Court will stay its injunction for the pendency of MSN's appeal. *Reilly*, 858 F.3d at 179. Although the Court need not address the balance of equities and public interest prongs, the Court references its prior Opinion and finds that because trade dress does not apply, those factors now also favor staying the Court's injunction. Opinion at 18 ("There is no question that MSN would suffer significant hardship if enjoined. . . . The Court is also mindful of the societal benefits of affordable alternatives to brand-name drugs and laments obstacles to such access.").

V. CONCLUSION

For the reasons stated above, the Court will **GRANT** MSN's Motion for a Stay Pending Appeal. An appropriate Order accompanies this Opinion.

Dated: May 22, 2025



Evelyn Padin, U.S.D.J.

⁶ Novartis itself agrees that when "the time between the request for a preliminary injunction and the court's decision on the merits" is limited, that time serves as "an important limit on the harm." PI Reply at 12 n.13.